

Applicants : Sharon Cohen-Vered et al.  
Serial No. : 10/758,272  
Filed : January 14, 2004  
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**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-11. (Canceled)

12. (Previously Presented) A pharmaceutical composition comprising

an aqueous carrier;

from 0.1 mg/ml to 2.5 mg/ml of the composition of an acetate salt of a peptide having the structural formula  
NH<sub>2</sub>-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly  
Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

from 70 mg/ml to 170 mg/ml of the composition of hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin or a salt of hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin,

wherein the peptide and the hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin or a salt of hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin are dissolved in the aqueous carrier; and

wherein the pharmaceutical composition has a pH between 6.5 and 8.5.

13. (Original) The pharmaceutical composition of claim 12, wherein the concentration of the acetate salt of the peptide is at least 0.5 mg/ml.

14. (Canceled)

15. (Original) The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 to 2.5 mg/ml.

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16. (Previously Presented) The pharmaceutical composition of claim 13, wherein the concentration of the salt of hepta-(sulfoethyl ether)- $\beta$ -cyclodextrin is 120 mg/ml, and wherein the pH of the pharmaceutical composition is between 7.5 and 8.5.
17. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 1.0 mg/ml.
18. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 2.5 mg/ml.
19. (Previously Presented) A method of alleviating symptoms of systemic lupus erythematosus (SLE) in a human subject comprising administering to the human subject the pharmaceutical composition of claim 12 in an amount effective to alleviate the symptoms of SLE in the human subject.
20. (Canceled)
21. (Currently Amended) A process for manufacturing ~~the~~ a pharmaceutical composition comprising the steps of:
  - a) preparing a solution of a hepta-(sulfoethyl ether)- $\beta$ -cyclodextrin or a salt of hepta-(sulfoethyl ether)- $\beta$ -cyclodextrin in an aqueous carrier at a predetermined concentration;

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- b) adding a predetermined amount of a pharmaceutically acceptable salt of the peptide NH<sub>2</sub>-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1) to the solution of step a);
- c) adjusting the pH of the solution of step b) until the peptide dissolves in the solution; and
- d) if necessary, adjusting the pH of the solution of step c) to a pH of 4-9, thereby manufacturing the pharmaceutical composition.

22-30. (Canceled)

31. (Previously Presented) A pharmaceutical composition prepared by the process of claim 21.

32. (Previously Presented) A process of lyophilizing the pharmaceutical composition of claim 12, comprising the steps of:

- a) lowering the temperature of the pharmaceutical composition to -40°C;
- b) holding the temperature at -40°C for a predetermined time;
- c) raising the temperature of the solution to 20°C;
- d) holding the temperature at 20°C for a predetermined time; and
- e) reducing the pressure in step d) to a pressure suitable for lyophilization and holding the temperature at 20°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

33-40. (Canceled)

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41. (Original) The process of claim 32, wherein  
step a) is performed within 2 hours;  
step b) is performed within 3 hours;  
step c) is performed over 13 hours and at a pressure of  
110μbar;  
step d) is performed over 13 hours and at a pressure of  
110μbar; and  
step e) is performed over 5 hours and the pressure is  
reduced to 10μbar.
42. (Previously Presented) A lyophilized pharmaceutical  
composition prepared by the process of claim 32.
43. (Previously Presented) A process of lyophilizing the  
pharmaceutical composition of claim 12, comprising the  
steps of:  
a) lowering the temperature of the pharmaceutical  
composition to -45°C;  
b) holding the temperature at -45°C for a predetermined  
time;  
c) raising the temperature of the solution to -20°C;  
d) raising the temperature of the solution to 25°C; and  
e) holding the temperature at 25°C for a predetermined  
time, thereby lyophilizing the pharmaceutical  
composition.
- 44-51. (Canceled)
52. (Original) The process of claim 43, wherein  
step a) is performed within 6 hours;

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step b) is performed within 3 hours;  
step c) is performed over 19 hours and at a pressure of  
150μbar;  
step d) is performed over 13 hours and at a pressure of  
150μbar; and  
step e) is performed over 8 hours and at a pressure of  
150μbar.

53. (Original) A lyophilized pharmaceutical composition  
prepared by the process of claim 43.

54-56. (Canceled)

57. (Previously Presented) A lyophilized pharmaceutical  
composition comprising  
a pharmaceutically acceptable salt of a peptide having the  
structural formula  
NH<sub>2</sub>-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly  
Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and  
a hepta-(sulfoethyl ether)-β-cyclodextrin or a salt  
thereof.

58. (Previously Presented) A packaged pharmaceutical  
composition comprised of:  
a packaging material; and  
the lyophilized pharmaceutical composition of claim 57.

59. (Previously Presented) The lyophilized pharmaceutical  
composition of claim 53, wherein the water content of the  
pharmaceutical composition is less than 5%.

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60. (Previously Presented) The lyophilized pharmaceutical composition of claim 59, wherein the water content of the pharmaceutical composition is less than 4.0%.
61. (Currently Amended) The lyophilized pharmaceutical composition of claim 60, wherein the water content of the pharmaceutical composition is less ~~then~~ than 3.5%.
62. (Previously Presented) The pharmaceutical composition of claim 12, wherein the pharmaceutical composition is iso-osmotic.
63. (Previously Presented) The pharmaceutical composition of claim 12 formulated for subcutaneous administration.
64. (Previously Presented) The pharmaceutical composition of claim 12 further comprising HCl or NaOH.
65. (Previously Presented) The pharmaceutical composition of claim 12 wherein the salt of hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin is a sodium salt.
66. (Previously Presented) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 0.5 mg/ml.